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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,370	03/15/2001	Yukino Owaki	204395US0XPC	7568

22850 7590 08/08/2003

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 08/08/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n No.

09/786,370

Applicant(s)

OWAKI ET AL.

Examiner

Sharmila S. Gollamudi

Art Unit

1616

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5,7 and 10-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7 and 10-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 12113.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of Request for Continued Examination, Amendment C, and Information Disclosure Statement received on May 20, 2003 and Information Disclosure Statement received on June 3, 2003 is acknowledged. **Claims 1-5, 7, and 10-19 are pending in this application.** Claim 6 is cancelled.

### ***Response to Arguments***

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection based on Amendment C.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 1-5, 7, and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuutoku Yakuhin Kogyo KK (JP 10-147521) in view of Kubo et al (5,827,528).**

Art Unit: 1616

JP discloses a cataplasm for reducing pain containing 1-30% lidocaine, 5-50% SIS, 5-60% liquid paraffin, and 1-60% alicyclic saturated hydrocarbon resin on a flexible base material. See page 1. The formulation may contain softeners such as polybutene and polyisobutylene. The inclusion of antioxidants and bulking agents such as titanium dioxide is also taught. See page 3. The base material has a thickness of 50-500 microns. See page 3.

JP does not specify the weight percent of butyl rubber in the formulation.

Kubo et al teaches a medical adhesive composition. The composition contains a thermoplastic elastomer such as SIS, a low compatibility thermoplastic elastomer such as butyl rubber/polyisobutene, a softener, and tackifier. Kubo teaches the tackifier may be a hydrocarbon resin, petroleum resin, or a terpene-phenol resin (col. 5, lines 15-28). Further, Kubo teaches the manipulation of the elastomers and softeners in the composition wherein the softener lowers the hardness of the elastomer. If the hardness is too high then the adhesive composition will not fit well on the skin (col. 6, lines 17-37). Note also embodiment 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Yuutoku Yakuhin Kogyo KK and Kubo et al and utilize butyl rubber in instant amount. One would be motivated to do so since Kubo teaches instant amount of polyisobutylene (butyl rubber) as thermoplastic elastomers for utilization with SIS in a pressure sensitive adhesive. Additionally, Kubo teaches the motivation of manipulating the amounts of the elastomers, softener, and tackifiers in the adhesive composition. Furthermore since Kubo teaches a similar

Art Unit: 1616

pressure sensitive adhesive patch with similar components as JP and JP teaches the inclusion of a butylene rubber, a skilled artisan would expect similar results and success by combining the teachings of the two references.

\*Note claims 2-5 and 10 have functional limitations on the product claims; therefore they do not hold patentable weight since the functional limitation does not recite a structural limitation on the product itself.

**Claims 1-5, 7, and 10-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sekisui Chem Co (JP 07-126157).**

JP teaches a percutaneous absorption tape for lidocaine. The formulation contains 40 weight section SIS, 20 weight section an alicyclic hydrocarbon resin, 40 weight percent liquid paraffin, and lidocaine. The formulation is placed on a film of 40 microns. See table 1. JP teaches an antioxidant in the formulation. The rubber system taught contains SIS and other rubbers such as polybutene, polyisoprene, isobutylene isoprene rubber, and natural rubber. See page 2.

JP does not specify the weight percent of butyl rubber in the formulation.

Kubo et al teaches a medical adhesive composition. The composition contains a thermoplastic elastomer such as SIS, a low compatibility thermoplastic elastomer such as butyl rubber/polyisobutene, a softener, and tackifier. Kubo teaches the tackifier may be a hydrocarbon resin, petroleum resin, or a terpene-phenol resin (col. 5, lines 15-28). Further, Kubo teaches the manipulation of the elastomers and softeners in the composition wherein the softener lowers the hardness of the elastomer. If the hardness

Art Unit: 1616

is too high then the adhesive composition will not fit well on the skin (col. 6, lines 17-37).

Note also embodiment 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of JP and Kubo et al and utilize butyl rubber in instant amount. One would be motivated to do so since Kubo teaches instant amount of polyisobutylene (butyl rubber) as thermoplastic elastomers for utilization with SIS in a pressure sensitive adhesive. Additionally, Kubo teaches the motivation of manipulating the amounts of the elastomers, softener, and tackifiers in the adhesive composition. Furthermore since Kubo teaches a similar pressure sensitive adhesive patch with similar components as JP and JP teaches the inclusion of a butylene rubber, a skilled artisan would expect similar results and success by combining the teachings of the two references.

\*Note claims 2-5 and 10 have functional limitations on the product claims; therefore they do not hold patentable weight since the functional limitation does not recite a structural limitation on the product itself.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (703) 308-2927. The fax phone numbers

Art Unit: 1616

for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG

  
August 4, 2003

  
MICHAEL G. HARTLEY  
PRIMARY EXAMINER